NATIONAL CONFERENCE *of* STATE LEGISLATURES

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March 13, 2014

Ms. Leslie Kux
Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Delivered electronically through http://www.regulations.gov

Re: Docket No. FDA-2013-N-0500

Dear Ms. Kux:

The National Conference of State Legislature (NCSL) submits the following comments regarding the Food and Drug Administration's proposed rule on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products. NCSL is a bi-partisan organization representing the legislatures of the nation's 50 states, its commonwealths, and its territories. We appreciate the opportunity to provide our views on this issue of critical importance to states.

The Food and Drug Administration (FDA) must establish a prescription drug safety process and strategy that: (1) provides strong oversight over both brand name and generic prescription drugs to ensure patient safety; (2) support the continuation of a strong and productive brand name and generic drug industry to ensure the continued development of new drug treatments and to ensure access to safe and effective drugs that are no longer manufactured by brand name prescription drug manufacturers; and (3) provides equitable recourse under state failure to warn laws for individuals that are injured by either a brand name or generic prescription drug.

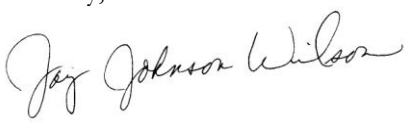
As the proposed rule accurately states, those who are harmed by the former, have recourse under state failure to warn laws pursuant to the U.S. Supreme Court case of Wyeth v. Levine, 555 U.S. 555 (2009). Those who are harmed by the latter, do not, pursuant to the U.S. Supreme Court case of Pliva v. Mensing, 131 S.Ct. 2567 (2011). NCSL participated as an amicus in the Wyeth and Pliva cases. NCSL recognizes that the holdings in these two cases create an inequitable situation for both states and their residents who use generic prescription drugs and we appreciate FDA's efforts to rectify the disparity between state failure to warn claims for brand name prescription drugs and generic prescription drugs. While state policymakers continue to strongly support the ability of its citizens to seek recourse to redress from harm regardless of the source, we do have concerns about how the proposed rule will impact overall drug safety, continued access to generic prescription drugs, the cost of generic drugs and the continued viability of the generic drug industry.

NCSL is concerned that the proposed rule as currently drafted, does not adequately take into account: (1) the ability of generic drug manufacturers to comply with the research and labeling requirements contained in the proposed rule; (2) the increased costs to the generic drug manufacturers to develop the capacity to perform the necessary research and to comply with the other requirements established in the rule; or (3) the additional costs that would be passed on to consumers. We also believe that the possibility of simultaneous multiple label changes for the same drug by different manufacturers, which the proposed rule would permit, will be confusing for doctors and patients.

We urge you to develop some alternative solutions for consideration, that would include the FDA, brand name prescription drug manufacturers and generic prescription drug manufacturers working together to ensure that as new information becomes available regarding the safety or efficacy of a generic prescription drug that the necessary label changes will be made expeditiously. If such a process would significantly change the way generic drug manufacturers would be required to conduct business, the impact of those changes should be addressed in any future rulemaking.

NCSL would be happy to work with the FDA to develop standards that would allow for those harmed by the use of generic prescription drugs to seek recourse and redress, while maintaining the safety of generic prescriptions drugs and the benefit of low-cost drugs to our citizens. We welcome the opportunity to work with you to achieve both goals. Please contact NCSL staff Joy Johnson Wilson (joy.wilson@ncsl.org) or Susan Parnas Frederick (susan.frederick@ncsl.org) or by phone at 202-624-5400, if NCSL can be of additional assistance to you.

Sincerely,



Joy Johnson Wilson
Director, Health and Human Services Policy